

CLAIMS

1. A pharmaceutical formulation which comprises a parenterally acceptable carrier or diluent, estramustine phosphate, a sulfoalkyl ether cyclodextrin and human albumin.
2. A formulation according to claim 1 wherein the weight ratio of estramustine phosphate to the sulfoalkyl ether cyclodextrin is from about 1:0.5 to about 1:5.
3. A formulation according to claim 1 or 2 which is in single infusion dosage form comprising at least 1300 mg, of the estramustine phosphate.
4. A formulation according to any one of the preceding claims which is in single infusion dosage form comprising at least 950 mg/m², of the estramustine phosphate.
5. A formulation according to any one of the preceding claims wherein the sulfoalkyl ether cyclodextrin is a straight or branched C₁-C₆ sulfoalkyl ether cyclodextrin.
6. A formulation according to claim 5 wherein the sulfoalkyl ether cyclodextrin is sulfobutyl ether β-cyclodextrin.
7. A formulation according to any one of the preceding claims for intravenous use.
8. A formulation according to any one of the preceding claims wherein the estramustine phosphate is in the form of a pharmaceutically acceptable salt for intravenous use.

9. A formulation according to claim 8 wherein the estramustine phosphate is in the form of N-methyl glucamine salt.
- 5 10. A formulation according to any one of the preceding claims for use in the treatment of cancer.
- 10 11. A formulation as claimed in claim 10 wherein the cancer is prostate cancer, breast cancer, melanoma, lung cancer, pancreatic cancer, colorectal cancer, ovarian cancer or cancer of the brain.
- 15 12. A formulation according to claim 1 wherein the estramustine phosphate is in admixture with the sulfoalkyl ether cyclodextrin and the human albumin.
- 20 13. A formulation according to claim 1 wherein
(i) the estramustine phosphate is in lyophilised form and the parenterally acceptable carrier or diluent is a physiological solution containing the sulfoalkyl ether cyclodextrin and the human albumin, or
(ii) the estramustine phosphate and sulfoalkyl ether cyclodextrin are in lyophilised form and the parenterally acceptable carrier or diluent is a
25 physiological solution containing the human albumin.
- 30 14. A product which comprises
(i) a pharmaceutical formulation which comprises a parenterally acceptable carrier or diluent and estramustine phosphate in admixture with a sulfoalkyl ether cyclodextrin and human albumin, and
(ii) one or more chemotherapeutic agents,
as a combined preparation for simultaneous, separate or
35 sequential use in anticancer therapy.
15. A product according to claim 14 wherein the sulfoalkyl ether cyclodextrin is sulfobutyl ether β -cyclodextrin.

16. A product according to claim 14 or 15 wherein the chemotherapeutic agent is selected from taxane, taxane derivatives, CPT-11, camptothecin and derivatives thereof, doxorubicin, idarubicin, epirubicin, etoposide, navelbine, vinblastine, carboplatin, cisplatin, Sugen SU 6668 and Sugen SU 5416.
17. A product according to claim 14 for intravenous use.
18. A product according to claim 14 for use in the treatment of prostate cancer, breast cancer, melanoma, lung cancer, pancreatic cancer, colorectal cancer, ovarian cancer or cancer of the brain.
19. A formulation as defined in claim 7 for use in suppressing or reducing the side-effects associated with the intravenous administration of estramustine phosphate and pharmaceutically acceptable salts thereof.
20. A formulation according to claim 19 wherein the side effects comprise ulcerative lesions and thrombophlebitis at the site of injection.
21. A product which comprises estramustine phosphate in lyophilised form and a physiological solution for parenteral use containing a sulfoalkyl ether cyclodextrin and human albumin.
22. A product which comprises estramustine phosphate and sulfoalkyl ether cyclodextrin in lyophilised form and a physiological solution for parenteral use containing human albumin.

23. Use, in the manufacture of a medicament for parenteral administration, of estramustine phosphate in admixture with a sulfoalkyl ether cyclodextrin and human albumin.

5 24. Use according to claim 23 wherein the medicament is for intravenous administration.

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